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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,598	01/06/2000	A. Gururaj Rao	5718-16A	1892

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/478,598	RAO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kathleen M Kerr	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 68,69,71 and 75-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68,69,71 and 75-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on April 6, 2004), Applicants filed a response and amendment received on July 6, 2004. Said amendment amended Claims 68 and 69. Thus, Claims 68, 69, 71, and 75-79 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 08/988,015 filed on December 10, 1997.

### ***Withdrawn - Claim Objections***

3. Previous objection to Claim 68 for lacking specific reference to the appropriate protein is withdrawn by virtue of Applicant's amendment.

### ***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

4. Previous rejection of Claims 68, 69, 71, and 75-79 under 35 U.S.C. § 112, second paragraph, as being indefinite for the redundant phrase "set of antibodies capable of binding with the native protein, wherein said antibodies recognize the native conformation of said protein" is withdrawn by virtue of Applicant's amendment.

5. Previous rejection of Claims 68, 69, 71, and 75-79 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's amendment.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

6. Previous rejection of Claims 68, 69, 71, and 75-79 under 35 U.S.C. § 112, second paragraph, as being indefinite for the nature of VSP $\beta$  is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the term VSP $\beta$  encompasses more than SEQ ID NO:1, that is encompasses "a very narrow genus" that is well known in the art. The Examiner disagrees that the metes and bounds of such a genus are known. No other species are noted in the specification, as previously noted. Clarification is required. For Claim 68, the phrase "which is VSP $\beta$ " indicates a single species. For Claim 69\*, the phrase "composition of VSP $\beta$ " also indicates a single species.

\*\*\* The Examiner notes that Claim 69 of the previous claim set (as amended on March 25, 2004) uses the phrase "composition of VSP $\beta$ " while the phrase in the presently pending claim set is "composition of a VSP $\beta$ " (emphasis added) despite the fact that no amendment was made (i.e., brackets are not around the [a] as required to insert the term). This only adds to the lack of clarity of the instant claims.

7. Previous rejection of Claims 68, 69, 71, and 75-79 under 35 U.S.C. § 112, second paragraph, as being indefinite is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the present language is in response to rejections under 35 U.S.C. § 112, 1<sup>st</sup> paragraph; the Examiner does not disagree, but the claims must be clear under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph. Applicant further argues:

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“The claims now require that the antibodies bind both the native protein and the engineered protein; one of skill in the art will appreciate that these additional limitations essentially require that the engineered protein will substantially retain the native conformation.”

This is exactly the Examiner’s point. Is native conformation retention required to meet all the limitations of the claim? As previously noted,

“The claim language is confusing because the specification focuses on altering the amino acid composition AND maintaining native conformation and activity (see page 4, lines 29-30); the instant claims are drawn to simply altering amino acid sequences and assessing (without any requirement for maintaining) native conformation. Such basic criteria are met when a protein is mutated and purified with polyclonal antibodies, for example, wherein the native conformation need not be maintained as long as particular epitopes are maintained. While the combination of mutation and maintaining native conformation is implied in the language of the claims and from the specification, it is unclear if such maintenance is a clear limitation of the claimed methods. Clarification is required.”

8. Previous rejection of Claims 68 and 71 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that as long as a single example of the claimed method with any amount of % alteration is described, that all possible percentages are described; the Examiner disagrees in part. The second issue concerning the antibodies recognizing native conformation has been obviated by Applicant’s amendment requiring the antibodies to merely bind native conformation.

However, the rejection is maintained as to the second part, which is only relevant to Claims 68 and 71. For Claims 68 and 71, the antibodies must bind the engineered protein and without an upper limit on the percentage altered, the genus is not described because antibodies

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that bind a VSP $\beta$  that is altered to 90% of its original sequence are not described. Additionally, not even a single species is described of a method that alters VSP $\beta$  by 10% (the example shows 8.3%) along with a set of antibodies that recognize the engineered protein. For these reasons, the instant claims lack adequate written description.

### ***Summary of Pending Issues***

9. The following is a summary of the issues pending in the instant application:
- a) Claims 68, 69, 71, and 75-79 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the nature of VSP $\beta$  (is it species or a genus).
  - b) Claims 68, 69, 71, and 75-79 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite as to whether native conformation must be maintained to meet all the limitations of the claimed methods.
  - c) Claims 68 and 71 stand under 35 U.S.C. § 112, first paragraph, written description, for altering by at least 10% and having a set of antibodies that bind such an engineered protein.

### ***Conclusion***

10. Claims 68, 69, 71, and 75-79 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

September 23, 2004